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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,996	04/20/2005	Yongren Benjamin Peng	58768.000007	8890

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,996	PENG ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34 and 36* is/are pending in the application.

4a) Of the above claim(s) *21-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 and 36 are pending in the application. Claims 21-34 are withdrawn. Claim 35 is cancelled and claim 36 newly added in the amendment filed 9/18/09.

Response to Arguments

1. Applicant's arguments, see remarks, filed 9/18/09, with respect to the rejection of claims 1-3,6,7,11-13,15 and 17 under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US2004/0131543A1) have been fully considered and are persuasive. The rejection of 1-3,6,7,11-13,15 and 17 has been withdrawn.

2. Applicant's arguments filed 9/18/09 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. There are two separate requirements set forth in this paragraph:

6. (A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and

bounds of the subject matter that will be protected by the patent grant. § MPEP 2171

7. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). The specification does not provide any guidance to distinguish "an effective amounts" necessary for the two distinct treatments, such as radiation synovectomy of arthritis and radiation therapy of a tumor and thus one skilled in the art cannot distinguish the metes and bounds of the instant claims. § MPEP 2171.01-0.2[R-1]. It is unclear on how much is necessary to provide an effective amount as claimed, given the lack of definition in the specification or the interpreting this as a term of art.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4,11,15-20 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Glajch et al. (US 6,455,024 B1) as stated in the office action mailed 6/18/09.

10. Applicant asserts that Glajch et al. does not teach of a resorbable base glass matrix.

11. The base glass matrix implant of Glajch et al. which is comprised of silicas, phosphates, etc., such as calcium phosphate anticipates the phosphate base glass matrix comprising calcium of the instant claims. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

12. Further, Glajch et al. teaches that the inorganic particles/base glass of the disclosure can be prepared with a range of different solubilities in aqueous fluid, such as body fluid. The solubility of the inorganic particles/base glass of the disclosure may affect the rate of biodegradation (Glajch et al. column 6, lines 30-45).

13. Applicant asserts that Glajch et al. is silent regarding a nitrogen-rich layer formed on the surface of a resorbable base glass matrix. Rather, Glajch et al. suggests that nitrogen may be incorporated into glass-through melting glass in anhydrous ammonia.

14. The instant claim 1 is a product-by-process limitation and therefore it is irrelevant as to how the nitrogen layer is formed. The patentability of a product does not depend on its method of production. Further, Glajch et al. teaches of nitriding the phosphate starting glass to produce glasses containing up to 12 wt% nitrogen which anticipates a nitrogen layer.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1-5,8,10-16,18-20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glajch et al. (US 6,455,024 B1) in view of Day et al. (US 5,011,797) as stated in the office action mailed 6/18/09.

17. Claims 1-5,8-11,13-16,18-20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glajch et al. (US 6,455,024 B1) in view of Gilchrist et al. (US 6,143,318) as stated in the office action mailed 6/18/09.

18. Applicant asserts that Day et al. and Gilchrist et al. are silent regarding the use of nitrogen, let alone forming a nitrogen-rich layer on the surface of a resorbable base glass matrix.

19. The references of Day et al. and Gilchrist et al. were not used to teach of the use of nitrogen or forming a nitrogen-rich layer on the surface of a resorbable base glass matrix but were used to teach that silicate glass particles may be used for the method of radiation synovectomy of arthritis and that selenium may be included into phosphate glass particles to promote wound healing, respectively. The reference of Glajch et al. teaches of nitriding the starting glass to produce glasses containing up to 12 wt% nitrogen which encompass a nitrogen layer.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 1-4,6,7,11-13,15-20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glajch et al. (US 6,455,024 B1) and in view of Wong et al. (US2004/0131543A1).

22. Glajch et al. (US 6,455,024 B1) discloses a particle/implant which is in a glass state and is comprised of silicas, phosphates, etc., such as calcium phosphate (column 5, lines 12-25 and 55-60) and radionuclides, such as ^{90}Y, ^{32}P, ^{33}P, ^{90}Sr (column 3, lines 22-35; column 5, lines 62+; examples 1-4). The phosphate may include a nitrogen rich layer containing up to 12 wt % nitrogen and the radionuclide may be distributed substantially uniformly throughout the inorganic material where the radionuclide of interest may be contacted with the particle via co-precipitation and therefore does not need or require high energy particle irradiation to convert one or more stable isotopes into radioactive isotopes (column 3, lines 22-35; column 4, lines 65-67; column 5, lines 45-53; column 9, lines 19-28). Co-precipitation is the process in which the radionuclide in a soluble form is intimately mixed with a soluble precursor of the inorganic material. The radionuclide and the inorganic materials are made to concurrently precipitate by means of changing the solvent, adding a precipitating solvent in which the radionuclide

and inorganic materials are not soluble, etc. (column 9, lines 56-62). The particles of the disclosure are encapsulated within a biocompatible material/nonconductive delivery vehicle, such as polyethylene terephthalate (PET) and may be used for the method of treating a tumor (i.e. brachytherapy) (column 1, lines 9-16; column 4, lines 9-14 and 47-50). The implants may be administered parenterally to a treat tissue or organ systems (column 1, lines 8-16; column 3, lines 8-13).

23. Glajch et al. does not disclose an image enhancing agent, such as gadolinium.

24. Wong et al. (US2004/0131543A1) discloses particles/microsphere radiopharmaceutical macroaggregates comprising a metal and one or more radioactive isotopes and which have sufficient radioactivity (p2, [0014]). The particles may be glass microspheres where the non-radioactive metal (i.e. Ca or Gd) and one or more radioactive isotopes are adsorbed by the glass material (p2-3, [0017]). The microsphere radiopharmaceutical macroaggregates are used for MRI, methods for the locoregional treatment of abnormal tissue (i.e. tumor, synovial tissue) and for acupuncture therapy of rheumatoid arthritis (p3, [0018] and [0022]; p4, [0037]; p10, [0076]; p11, [0079]). The microsphere radiopharmaceutical macroaggregates are prepared via coprecipitation of phytate (Inositol hexaphosphate) a non-radioactive cation, a radionuclide cation (^{90}Y) and a radionuclide anion (^{99m}Tc) (p6, [0053]). The radiopharmaceutical macroaggregates have radioactivity levels of about 1 microcurie to about 500 mCi (p8, [0064]).

25. At the time of the invention it would have been obvious to one ordinarily skilled in the art to include a metal, such as gadolinium as taught by Wong et al. in the glass

particle/implant of Glajch et al. for the advantage of allowing for the accurate measurement of geographical distribution of the particles/implants in the injected and surrounding tissues (Wong et al. p2, [0015]) as both disclosures are drawn to the same utility, such as the treatment of a abnormal tissue, tissue, tumor, etc.

Conclusion

26. No claims are allowed at this time.

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618